3M Health Care

3M Center
St. Paul, MN 55144-1000
651 733 1110

3M August 24, 2000

VIA EXPRESS COURIER

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Attn: Docket No. 00D-1318

Subject: Draft Guidance for Industry on Chronic Cutaneous Ulcer and Burn Wounds – Developing Products for Treatment

Dear Sir or Madam:

3M Health Care is providing the following comments to the subject Draft Guidance document, solicited by FDA in the Federal Register of June 28, 2000:

Section II.B.1:

Complete wound closure is defined as "skin closure without drainage or dressing requirements." We suggest that *complete wound closure* instead be defined as "100% epithelialization, without drainage," because some clinicians continue to advise dressing use over a closed wound for protection from trauma to the newly healed surface.

The draft guidance requests a 3-month follow-up of patients after complete closure of the wound being treated. We believe that this length of time is unduly burdensome, both to industry and to the patient. Patients recruited for a clinical study of chronic ulcers, for example, would not want to make a trip to the investigator's office after 3 months, especially if their wound were closed and they were doing well. A more practical endpoint for durability of closure is a 1-month follow-up. If industry were held to valid 3-month endpoints, the dropout rate for the study would be high and additional recruitment would lengthen the trial considerably. This would affect time-to-market of valuable treatments and would produce a higher research cost for industry due to higher costs for such studies.

Section II.B.2:

The guidance states ". . .the time to wound closure is most meaningfully compared when the incidence of complete closure is the same in both arms." If analyzed in this

manner, the only products that could claim *accelerated wound closure* wound be those that have no benefit in *improved incidence of closure*. Because *improved incidence of closure* and *accelerated wound closure* are measured separately, we see no reason that both claims should not be allowed if the data support the definitions.

Section II.C.2:

We agree with FDA in that *partial debridement* is not an acceptable endpoint for success with debriding agents. The term *thorough debridement* is certainly more appropriate but still needs further definition. For consideration, the definition might be "Thorough debridement is the removal of all necrotic tissue in the wound."

Section IV.C.4:

The draft guidance states that biopsy of the wound to assess infection versus colonization is preferred to culture of swab specimens. To our knowledge biopsy of a wound is not widely practiced and would not be performed by most clinicians. We believe that presence of infection can be determined, for most cases, on the basis of swab cultures and clinical symptoms.

Section IV.E:

Although consistent standard care may allow a more statistically meaningful analysis of data from wound trials, there is a lack of universal consensus regarding "best practices." In an effort to provide guidance, the Agency has attempted to elaborate on specific items that it has interpreted as being best practice. While it is theoretically important to analyze the effect of common variations in *standard care* on the experimental treatment, this would require an unusually large number of patients for stratification and meaningful interpretation. For these reasons, we suggest that FDA minimize specific suggestions regarding *standard care* until the appropriate professional groups adopt standard care protocols for respective wound categories.

We hope these comments are useful to the Agency in writing the Final Guidance.

Respectfully,

Anna McRight

Anna McRight
Product Regulation Manager
3M Health Care

Shipping Ticket

Sender - Original copy MUST accompany shipment. Peel off liner from label and attach rest of set to package (do not tape).

Domestic Use Only

From	Bldg. - Fl	Dept. Charge	Serial No.
Anna McRight	275-5W-06	9118	05398600
	Phone 3-7948		

3M

3M General Offices - 3M Center - St. Paul, MN 55144-1000
Contents Merchandise
Return or Forwarding Postage Guaranteed

Post master: This parcel may be opened for postal inspection if necessary. If not delivered in 10 days, return package to us, but not before the expiration of 10 days regardless of reason for non-delivery.

05

SHIPPING
3M CO
216-1S, BLDG 216
ST PAUL MN 55144
(651)733-6397

SHIP DATE: 24AUG00
ACC # 0554008709

ACTUAL WGT: 4 LBS SCALE

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Docket No. 00D-1318

SEE ADDRESS LABEL ON PACKAGE FOR THIS SHIPMENT TO MD 20852

4793 5574 3917 FedEx.

4793 5574 3917

REF: P 19118722 05398600

PRIORITY OVERNIGHT FRI

cad # 0085471 24AUG00 FORM 0201

TRK# 4793 5574 3917

Deliver by: 25AUG00

IAD AA

20852 -MD-US 19 GAIA

153078-077 RIT 06/00 •